



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

Telephone: 504-253-4519
FAX: 504-253-4520

April 7, 2003

WARNING LETTER NO. 2003-NOL-15

**FEDERAL EXPRESS
OVERNIGHT DELIVERY**

Mr. Gary Marshand, CEO
Memorial Hospital at Gulfport
Blood Bank
4500 13th Street
Gulfport, Mississippi 39501-2569

Dear Mr. Marshand:

During an inspection of your blood transfusion service, located at 4500 13th Street, Gulfport, Mississippi, on March 5, 6 and 10, 2003, our investigator documented deviations from Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) and the Current Good Manufacturing Practice (CGMP) regulations for blood and blood components and finished pharmaceuticals under Title 21, *Code of Federal Regulations* (CFR), Parts 210 - 211 (21 CFR 210 - 211) and 600-680 (21 CFR 600 - 680). You can find the Act and the other regulations through links in FDA's home page at <http://www.fda.gov>.

The deviations documented were as follows:

- On June 12 and November 5, 2001, your facility did not document the disposition of units exposed to temperatures above 12°C for over 30 minutes. In addition, your facility failed to maintain an inventory of blood units held in storage on those same dates [21 CFR 606.160(a)(1) and 606.160(a)(2)(b)(3)(i)];
- Your facility failed to have a written standard operating procedure in place to document the amount of time blood units are not refrigerated when the units are removed from the blood bank, irradiated, and then returned back to the blood bank [21 CFR 606.100(b)(10)];
- Your facility failed to notify the attending physician of a recipient who received a unit of whole blood, that was collected from a donor who tested positive for anti-Hepatitis C virus (21 CFR 610.47);
- Your facility failed to adhere to your written standard operating procedures in that you did not provide supervisory review of the reagent quality control records [21 CFR 606.100(c) and 211.194(a)(8)]; and,


- Your facility has failed to maintain the [REDACTED] in accordance with your written standard operating procedures. Specifically, your standard operating procedure requires cleaning the [REDACTED] on a monthly basis; however, the washer has not been cleaned since August 12, 2002 [21 CFR 606.60(a)].

The above deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all blood products issued by your facility are in compliance with the Act and the CGMP regulations. You should take prompt action to correct these deviations. Your failure to correct these deviations may result in regulatory action being taken by FDA without further notice. Possible actions include license suspension and/or revocation, seizure, and/or injunction.

We are aware that during the inspection, [REDACTED] made a verbal commitment to correct violations observed at your firm. However, we request that you notify this office in writing, within fifteen (15) working days of receipt of this letter, of specific steps you have taken to correct these deviations, including examples of any documentation such as employee training records, written standard operating procedures or other records demonstrating corrective action. If you cannot complete corrections within 15 working days, state the reason for the delay and the time period within which corrections will be completed.

Your reply should be directed to Mark W. Rivero, Compliance Officer, at the above address.

Sincerely,


Patricia K. Schafer
Acting District Director
New Orleans District

Enclosure: Form FDA 483

cc:

Memorial Hospital at Gulfport - Blood Bank
4500 13th Street
Gulfport, Mississippi 39501-2569